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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,415	11/22/2005	Wolfgang Berdel	20057.002	2682
28381	7590	11/16/2010		
ARNOLD & PORTER LLP				
ATTN: IP DOCKETING DEPT.				
555 TWELFTH STREET, N.W.				
WASHINGTON, DC 20004-1206				
EXAMINER				
REDDIG, PETER J				
ART UNIT		PAPER NUMBER		
1642				
NOTIFICATION DATE		DELIVERY MODE		
11/16/2010		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IP.Docketing@aporter.com

### Office Action Summary

**Application No.**

10/531,415

**Applicant(s)**

BERDEL ET AL.

**Examiner**

PETER J. REDDIG

**Art Unit**

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 August 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 37-39, 41-53, 61-64 and 73-77 is/are pending in the application.
- 4a) Of the above claim(s) 61-64 and 73-76 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 37-39, 41-51, 53 and 77 is/are rejected.
- 7) ☒ Claim(s) 45 and 52 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. The Amendment filed August 23, 2010 in response to the Office Action of February 22, 2010 is acknowledged and has been entered. Previously pending claims 1-36, 40, 54-60, and 65-72 have been cancelled, claims 37-39, 41-53 and 77 have been amended and claims 61-64 and 73-76 were previously withdrawn. Claims 37-39, 41-53 and 77 are currently being examined.

#### ***New Grounds of Rejection***

#### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 37-39, 41-51, and 77 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 37-39, 41-51, and 77, as written, do not sufficiently distinguish over the claimed polypeptide compounds as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed fusion proteins and naturally occurring fusion proteins. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). In order to obviate the instant rejection, the Examiner suggests that the claims should be amended to indicate the hand of the inventor, e.g., by insertion of "isolated" or "purified" provided the support for such an amendment can be identified in the specification as originally filed. See MPEP 2105.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 53 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 53 recites the limitation "the compound" in reference to the parental claim. There is insufficient antecedent basis for this limitation in the claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 37 and 50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 50 is drawn to the fusion protein of claim 37, wherein the first binding domain comprises the peptide sequence of the c-myc DNA binding domain and defines an embodiment of claim 37. Claim 37 was amended to require the first binding domain to bind one molecule selected from the group consisting of AML 1-ETO, BCR-Abl, PML-RARalpha, PLZF-RARalpha, and EWS-FLI. The specification as filed did not describe a c-myc DNA binding domain having the ability to bind said molecules. Thus, the amendments broaden the scope of the invention as originally disclosed in the specification and is new matter.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 37, 44, 45, and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Coutinho et al. (Blood 2000: 96: 618-624) evidenced by McWhirter et al. (Mol. and Cell. Biol. 1993, 13: 7587-759, previously cited).

Coutinho et al. teach a fusion protein of Grb4-EYFP. Coutinho et al. teaches that Grb4 alters the distribution of BCR-ABL in Cos-7 cells from actin filaments, stress fibers, and juxtanuclear punctuate aggregates to non-juxtanuclear punctuate aggregates. See Abstract, Subcellular localization of Grb4, p. 622-623 and Fig. 7. Coutinho et al. teach that Grb-4 binds Bcr-Abl through an SH2 domain and an SH3 domain. See Abstract, Figs. 1 & 5, p.621, and P. 623-1<sup>st</sup> col. Thus the binding of either domain of GRB4 contributes to the dyslocalization of BCR-Abl.

McWhirter et al. teach that BCR-Abl normally localizes to F-actin. See Abstract, p. 7587-2<sup>nd</sup> col. and Fig. 6.

***Claim Objections***

6. Claim 45 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 45 is drawn to the fusion protein of claim 37,

where the molecule is a fusion protein. The molecules currently claimed in the Markush group of claim 37 are all fusion proteins. Thus, claim 45 does not further limit claim 27.

7. All other objections and rejections recited in the Office Action of February 22, 2010 are withdrawn.

8. Claims 37-39, 41-51, 53 and 77 are rejected.

9. Claim 52 is objected to for depending on a rejected base claim.

10. No claims allowed.

11. Applicant's amendment necessitated the new grounds of rejection. Thus **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Reddig whose telephone number is (571) 272-9031. The examiner can normally be reached on M-F 8:30 a.m.-5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Misook Yu can be reached on (571) 272-0839. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Peter J Reddig/  
Primary Examiner, Art Unit 1642